

REMARKS/ARGUMENTS

Applicants thank the examiner for the interview granted on August 5, 2004, in which the above-claim amendments were generally discussed.

Applicants have amended the claims so that they affirmatively recite inherent properties of the claimed metabolites. Applicants have also added two new claims, as described in detail below.

35 U.S.C. § 112 – Indefiniteness

The examiner rejected Claim 40 under 35 U.S.C. § 112 as indefinite because the words "the isolated *Streptomyces* sp. strain" lack antecedent basis. Applicants have amended Claim 40 so that it refers to "the biologically pure *Streptomyces* sp. strain" and is, therefore, consistent with Claim 1, from which it depends. This amendment renders the rejection moot. Therefore, Applicants respectfully request that it be reconsidered and withdrawn.

35 U.S.C. § 102 – Anticipation

The examiner also maintained her previous rejection of Claims 1-10, 12-16, 18-31 and 40 under 35 U.S.C. § 102(b) as anticipated by the Breinholt reference. By this amendment, Applicants have cancelled Claims 6-9, 11, 17 and 25-28, thereby rendering the rejection moot as to them.

Applicants have amended Claim 1 so that it recites the UV absorption and also the non-aromatic nature of the claimed metabolites. These claim amendments are fully supported by the specification. Specifically, support for the limitation reciting UV absorption at about 215 nm to about 220 nm is found, e.g., at page 19, lines 28-29. Support for the limitation reciting the non-aromaticity of the compounds is provided, e.g., in Figures 1B and 2B. These figures show UV absorption by the metabolites at about 215 nm and about 220 nm but not at the wavelengths at

which aromatic compounds necessarily show absorption. In addition, at page 18, lines 1-8, the specification notes that neither porfiromycin, a purple compound, nor aromatic heptaenic trichomycin has the UV spectra of the claimed metabolites. This is because both are aromatic compounds, as fully described in the references cited in relation to each compound.

The UV absorption exhibited by the claimed metabolites is also different from the UV absorption of the aromatic Breinholt compounds. The compounds of Breinholt, which are described at column 3, lines 60-63 of the Breinholt patent (USP 5,641,804) as "pentalactones being unique in having *aromatic* hydroxy acids incorporated in the ring structure," each exhibit UV absorbance at 303 nm, 265 nm and 217 nm. See Breinholt, column 12, line 24. This UV absorbance at 265 nm and 303 nm is an inherent property of the Breinholt compounds and indicative of their aromaticity. In contrast, the metabolites of the present invention show UV absorption between about 215 and about 220 nm but not at 265 nm and 303 nm. (See, for example, Figure 1B.) The claimed metabolites would not lack absorption at 265 nm and 303 nm if they had the aromatic structure of the Breinholt compounds.

Because Breinholt does not disclose each and every element of Claim 1, as amended, it does not anticipate Claim 1 or Claims 2-5, 10, 12-16, 18-24, or 29-31, and 40, which depend from Claim 1. Therefore, Applicants respectfully request that this rejection be reconsidered and withdrawn.

35 U.S.C. § 103 – Obviousness

The examiner also maintained her rejection of Claims 1-10, 12-16, 18-31 and 40 under 35 U.S.C. § 103 as obvious in light of Breinholt. By this Amendment, Applicants have cancelled Claims 6-9, 11, 17, 25-28 and 36-39, thereby rendering the rejection moot as to them.

To establish a prima facie case of obviousness, "the prior art reference...must teach or suggest all the claim limitations." MPEP § 2142. As discussed above, Breinholt does not disclose all elements of Claim 1, as amended. Therefore, Applicants submit that Claim 1, as amended, and dependent Claims 2-5, 10, 12-16, 18-24, 29-31 and 40 are not obvious in view of the Breinholt reference.

#### Other Claim Amendments and New Claims

##### *Claims 32-35*

Applicants have amended Claim 32, which was previously withdrawn, and have re-presented Claims 33-35, which depend from Claim 32. Claim 32, as amended, recites a method for isolating the metabolite of Claim 1. Because Claims 32-35 now depend from Claim 1, Applicants submit that they are no longer subject to the restriction requirement and request that they be re-joined.

##### *Claims 41-42*

Applicants have added new claims 41-42, which both depend from Claim 1. These newly added claims are fully supported by the specification. For example, support for Claim 41 is provided at page 6, lines 15-17. Support for Claim 42 is found, e.g., at page 8, lines 16-18.

The term "composition" is defined in the specification at page 6, lines 15-16 as a combination of active agent and *another compound*. Applicants have added Claim 41 to encompass all compositions that comprise the claimed metabolites and not only those compositions recited in Claims 12-13 in which the "another compound" is limited to a carrier.

Claim 42 simply recites a particular use of the metabolite. This use is also reflected in the method claims.

**CONCLUSION**

In light of the above-amendments and remarks, Applicants believe that each of the presently pending claims in this application is in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicants do not believe any fees are required by this submission, but if Applicants are mistaken, any required fees may be charged to deposit account 50-2767. If the Examiner has any questions regarding this communication, she is invited to contact the undersigned at (916) 444-3900, x353.

Respectfully submitted,

Dated: August 27, 2004

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